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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,420	11/26/2003	Stanley Beames Brown	0001530USQ/3049	2642

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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,420	BROWN ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-53,65-97* is/are pending in the application.

4a) Of the above claim(s) *44-53,65-76,80-83,85-88,92,94,96 and 97* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *77-79,84,89-91,93 and 95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12 May 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 44-53 and 65-97 are presented for examination.

Applicant's Amendment filed May 12, 2006 has been received and entered into the present application. Accordingly, the priority information at line 1 of the specification has been amended. Applicant's submission of a certified copy of PCT Application No. PCT/GB02/02278 is acknowledged and has been entered into the application. Applicant's Information Disclosure Statement (IDS) filed May 12, 2006 has also been received and entered into the application. As reflected by the attached, completed copy of form PTO-1449 (one page total), the Examiner has considered the cited references.

Claims 44-53 and 65-97 remain pending in the application. Claims 77-79, 84, 89-91, 93 and 95 are under currently under examination and claims 44-53, 65-76, 80-83, 85-88, 92, 94 and 96-97 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b) and the requirement for restriction dated April 11, 2005.

Applicant's arguments, filed May 12, 2006, directed to the rejections set forth under 35 U.S.C. 112, second paragraph, and the prior art rejections set forth under 35 U.S.C. 102 and 35 U.S.C. 103, have been fully considered and are persuasive. Accordingly, the rejections have been withdrawn. The following rejections and/or objections are newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Subject Matter Free of the Prior Art

The Examiner has performed a comprehensive search of the prior art at the time of the present invention and has determined that the presently claimed genus of compounds for the

presently claimed methods of use is free of the prior art. At the time of the present invention, the prior art is silent as to a teaching or fair suggestion of the use of such a genus of compounds for these presently claimed uses. In light of such, the subject matter of claims 77-79, 84, 89-91, 93 and 95 is free of the prior art, but is not in condition for allowance in light of the following considerations under the enablement requirement of 35 U.S.C. 112, first paragraph, and the requirements of 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

(New Ground of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 77-79, 84, 89-91, 93 and 95 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of fungal infections due to *Candida albicans*, gram-negative bacterial infections due to *E. coli* or *P. aeruginosa*, gram-positive bacterial infections due to *S. aureus* or methicillin resistant *S. aureus*, does not reasonably provide enablement for the treatment of microbial infections in general (including dental bacterial disease, skin or local infections in general) or the sterilization of surfaces or fluids in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the unpredictability or unpredictability of the art;
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art.

The relevant factors are addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

The presently claimed invention is directed to methods for treating microbial infections, antimicrobial treatment for skin and other local infections, sterilization of burn wounds and other lesions or dental bacterial disease comprising the administration to a subject in need thereof by systemic administration or by application to the area to be treated, a therapeutically effective amount of a claimed phenothiazinium dye compounds of Formula (I) and exposing said area to light to render the dye compound active (see present claims 77-78, 89-91, 93). The presently claimed invention is further drawn to methods for sterilizing surfaces or fluids comprising contacting or applying a dye compound of Formula (I) to said surface of fluid to be sterilized and then activating the compound by exposing the compound to light.

In particular, one skilled in the art could not practice the presently claimed subject matter without undue experimentation because the artisan would not accept on its face that the treatment

of any microbial infection (including dental bacterial disease, skin or local infections) in general or sterilization of any surface or fluid in general could actually be achieved. Based upon the state of the art, as discussed below, the artisan would have only accepted that the treatment of specific microbial infections or sterilization of particular surfaces or fluids could be achieved with the presently claimed phenothiazinium dye compounds.

As set forth in *In re Marzocchi et al.*, 169 USPQ 367 (CCPA 1971):

"[A] [s]pecification disclosure which contains teachings of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with the enabling requirement of first paragraph of 35 U.S.C. 112, *unless there is reason to doubt the objective truth of statements contained therein which must be relied on for enabling support;* assuming that sufficient reasons for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in the specification is truly enabling." (emphasis added)

The present claims circumscribe a method for treating any type of microbial infection or a method for sterilizing any surface or fluid. That is, in order to be enabled to practice the present invention, the skilled artisan would have to accept that by administering the presently claimed phenothiazinium compounds and activating them by exposing them to light that such therapeutic objectives could actually be achieved. However, in light of the fact that the specification fails to provide the skilled artisan with any direction or guidance as to how the treatment of microbial infections *in general* or the sterilization of any surface or fluid *in general*,

the present specification is viewed as lacking an enabling disclosure of the entire scope of the claimed invention.

Regarding the treatment of any type of microbial infections or the sterilization of any surface or fluid, the objective truth that any microbial infection may be treated or that any surface or fluid may be sterilized using the presently claimed phenothiazinium compound is doubted because the state of the art expressly recognizes the obstacles of antimicrobial therapies. While the state of the art with regard to the treatment of specific types of microbial infections using particular genus of chemotherapeutic antimicrobial agents is relatively well-developed, the state of the art with regard to the broad-spectrum treatment of any microbial infection using a single agent or a single genus of functionally similar agents is grossly underdeveloped and unpredictable, such that such an allegation would have been an outcome not reasonably expected by the skilled artisan.

It is in this regard that Mutschler et al. (Drug Actions: Basic Principles and Therapeutic Aspects; 1995) is cited. Mutschler et al. teaches anti-infective agents known in the art to exert their effects through one of the following four mechanisms of action: (1) inhibition of cell wall synthesis, (2) altered permeability of the cytoplasmic membrane, (3) blockade of protein biosynthesis, and (4) suppression of nucleic acid synthesis. According to Mutschler et al., the term "microorganism" or "microbe" ranges widely to encompass bacterial infections (e.g., cholera, diphtheria, gonorrhea, pertussis, leprosy, scarlet fever, syphilis, etc.), mycoses, diseases caused by protozoa, viral diseases (e.g., measles, German measles, herpes simplex and zoster, flu, poliomyelitis, etc.) and also vermiform diseases (see paragraph bridging pages 515-516).

However, therapies effective for a particular type of infection, for example, a bacterial infection, are not necessarily effective for infections of a different kind. As Mutschler et al. teaches, "Chemotherapy of viral diseases (and malignant tumors) is only possible to a limited extent, whereas effective substances are available for bacterial infections, mycoses and protozoan diseases, as well as vermiform attack." (third paragraph, page 516, column 1)

Mutschler et al. teaches a variety of chemotherapeutic anti-infectives, including antibacterial agents (i.e., beta-lactam antibiotics, aminoglycosides and aminocyclitol derivatives, tetracyclines, macrolides, nitroimidazoles, nitrofurans, chloramphenicols, lincosamides, fusidic acid, glycopeptides, fosfomycin, mupirocin, etc.), antimycotic agents (i.e., azole antimycotics, polyene antibiotics, griseofulvin, flucytosine, ciclopirox olamine, etc.), antiprotozoan agents (i.e., quinolines, primaquine, pyrimethamine, sulfonamides, etc.) and antiviral agents (i.e., amantadine, idoxuridine, vidarabine, acyclovir, ganciclovir, zidivudine, etc.) at pages 515-580, each of which differs significantly in structure, activity, and microbial indication.

It is clear from the discussion presented in Mutschler et al. that each compound or genus of chemically similar compounds has a discrete indication as to what type of microbe the compound is actually effective to treat, i.e., aerobic or anaerobic organisms, gram-negative or gram-positive organisms, proliferating or non-proliferating organisms, etc. For example, as Mutschler et al. teaches, aminoglycosides, polypeptides and beta-lactam antibiotics are each bactericidal (i.e., they reduce the number of pathogens rather than being bacteriostatic, which is the inhibition of pathogen proliferation) antibacterial agents, but aminoglycosides and polypeptides differ significantly from beta-lactam antibiotics in that they kill non-proliferating

microorganisms, whereas beta-lactam antibiotics are only effective against proliferating microorganisms (second paragraph, page 516, column 2).

Thus, it is obvious that the potency of antimicrobial effect is directly dependent on the proper assignment of a particular anti-infective agent for the treatment of only those microbes for which the compound is actually effective, since Mutschler et al. makes it clear that not all anti-infective agents known in the art have broad spectrum activity in treating any microbe that exists. In fact, Mutschler et al. teaches that the use of anti-infective agents broadly with disregard to their actual activity against particular microbes is improper and results in resistance, a dangerous circumstance that can prove to be fatal to patients and detrimental to the environment, as microbial resistance encourages growth of microbes that are insensitive to known anti-infectives and cannot be eradicated. "Each chemotherapeutic agent requires a *strict indication* since application of chemotherapeutic agents which is neither critical nor indicated can lead to unnecessary development of resistance, aggravate further diagnosis by masking the infection, damage to the flora of the mouth and intestine, and precipitation of avoidable allergic and toxic side effects. Especially for serious infections, a *susceptibility test* (antibiogram) should be performed if possible. The choice of appropriate drugs is facilitated by the application of quantitative agar or broth dilution tests. In contrast to the agar diffusion test, quantitative procedures make it possible to determine the MIC, which can then be related to the concentration obtainable in vivo (serum or tissue level)." (first paragraph, page 518, column 2)

In light of such teachings, the circumstances of effective anti-infective therapy are highly complex and must take into consideration many factors, including the type of organism to be treated, the mechanism of action of the agent, the susceptibility of the microbe to the selected

agent and the potency of the agent as measured by the MIC (minimum inhibitory concentration) or MBC (minimum bactericidal concentration). In other words, the state of the art with regard to the treatment of microbial infections is highly complex and unpredictable such that the activity of one agent in treating a particular type of microbial infection does not necessarily translate into the same level of activity, or even any effect whatsoever, against a distinctly different type of microbe. That is, the state of the art clearly dictates against the assertion that a single agent, in the present case, the instantly claimed phenothiazinium dye compounds, would have efficacy in treating any microbial infection that may exist in the art, absent adequate direction or guidance as to how such an objective may be achieved with a reasonable expectation of success.

The same reasoning applies to the sterilization of any surface or fluid. Practicing sterilization in an effort provide anti-microbial therapy to a surface, whether human or inanimate, or a fluid, whether human or inanimate, circumscribes the same unpredictability as treating a microbial infection for the same reasons as discussed above as it applies to anti-infective treatment of humans. Additionally, however, sterilization of surfaces and fluids must also taken into account the article that is actually being sterilized, what microbes are intended to be eradicated, and whether the integrity and natural state of the surface or fluid can be maintained throughout the sterilization process without significantly altering its structure or function as a result of the process such that its viability would be destroyed.

It is clear from the discussion above that the state of the art with regard to the treatment of microbial infections or the sterilization of surfaces or fluids is highly unpredictable. The amount of guidance required to be present in the specification as originally filed is directly proportional to the amount of knowledge in the art as well as the unpredictability in the art. In

other words, if little or nothing is known in the prior art about an aspect of the claimed invention and the art is unpredictable, the specification requires more detail and guidance as to how to use the invention in order to be enabling. Please reference *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) and *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004).

Applicant provides examples solely directed towards the specific treatment of fungal infections due to *Candida albicans*, gram-negative bacterial infections due to *E. coli* or *P. aeruginosa*, gram-positive bacterial infections due to *S. aureus* or methicillin resistant *S. aureus* (see Examples beginning at page 19 of the present disclosure). However, the instant specification conspicuously lacks any disclosure or teaching of manner and process of using the presently claimed phenothiazinium dye compounds for achieving the objective of treating microbial infections (including dental bacterial disease, skin or local infections in general) in general or the sterilization of any surface or fluid in general.

While a lack of a working embodiment cannot be a sole factor in determining enablement, the absence of substantial evidence commensurate in scope with the breadth of the presently claimed subject, in light of the unpredictable nature of the art and the direction that Applicant has presented, provides additional weight to the present conclusion of insufficient enablement in consideration of the *Wands* factors as a whole. Nowhere does the specification set forth how such compounds could be used for the treatment of any microbial infection, including bacterial infections, mycotic infections, protozoal infections, viral infections or vermiform infections, including, but not limited to, how susceptibility of the pathogen could be determined, what concentrations would be effective or even the route or frequency of administration, such

that the skilled artisan would have been imbued with at least a reasonable expectation of success in determining the activity of the presently claimed agents against any microbe without the burden of an undue level of experimentation. The specification also does not set forth what surfaces or fluids can be sterilized, what microbes could be targeted with the claimed dye compounds or the manner and process of actually performing the sterilization while maintaining the viability of the surface or fluid for use. Due to the unpredictable nature of microbial infections and the high degree of variability in activity and potency of anti-infective therapies, in the absence of any guidance or direction as to how the skilled artisan would go about treating any microbial infection in general or the sterilization of any surface or fluid in general, the instant disclosure is viewed as lacking enablement and requiring an undue level of experimentation for this aspect of the invention.

The basis for the present rejection is not simply that experimentation would be required, since it is clear from the state of the prior art and Applicant's disclosure that experimentation in this particular art is not at all uncommon, but that the experimentation required in order to practice this aspect of the invention would be *undue*. Please reference *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976), which states, "The test of enablement is not whether any experimentation is necessary, but whether, *if experimentation is necessary, it is undue*." (emphasis added) Applicant fails to address the unpredictability in the art by providing adequate direction or guidance as to how to practice this aspect of the invention, in terms of disclosing how to use the presently claimed phenothiazinium compounds such that the treatment of microbial infections in general or sterilization of any surface or fluid could be reasonably achieved, or even any basis for extrapolating the results shown in the Examples to the larger and

more highly varied genus of microbial infections or surfaces or fluids in general. As a result, the specification is viewed as lacking an enabling disclosure of the same.

In view of the discussion of each of the preceding seven factors, the level of skill in the art is high and is at least that of a medical doctor with several years of experience in the art.

As the cited art and discussion of the above factors establish, practicing the claimed invention in the manner disclosed by Applicant would not imbue the skilled artisan with a reasonable expectation that the treatment of microbial infections in general or the sterilization of surfaces or fluids in general could be achieved. In order to actually achieve such a result, it is clear from the discussion above that the skilled artisan could not rely upon Applicant's disclosure as required by 35 U.S.C. 112, first paragraph, and would have no alternative recourse but the impermissible burden of undue experimentation in order to practice the full scope of the embodiments of the presently claimed invention.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 77-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. I n particular, Applicant has claimed a "method of treatment of...burn wounds and other lesions", but fails to actually recite what is being treated. The actual therapeutic objective of the treatment of a burn wound or other lesion is not clearly set forth in the claim.

Applicant has also failed to set forth in a reasonably clear, deliberate or precise manner what types of lesions would be included or excluded from the phrase "other lesions" such that the skilled artisan would have been reasonably apprised of the metes and bounds of the claimed subject matter and would have been able to readily determine what would constitute infringement of the present claims.

The present disclosure discusses a number of different types of lesions within the present disclosure, including but not limited to, those lesions that result from cancer, ulcers, surgical wounds, nail infections, etc., but fails to provide a limiting definition as to what other lesions are intended to be treated by the presently claimed methods. As a result, Applicant's failure to set forth a reasonably clear, deliberate or precise definition of what lesions are intended to be included or excluded from the claims leaves such a limitation open to subjective interpretation, which is inconsistent with the tenor and express requirements of 35 U.S.C. 112, second paragraph.

Additionally, Applicant has also failed to set forth exactly what therapeutic indication is being treated in such "other lesions". It is clear that the skilled artisan would not readily understand what other lesions were actually encompassed by the claims and to what therapeutic end the presently claimed dye compounds were being used to achieve.

Lastly, it is noted that Applicant has not set forth in a clear, deliberate or precise manner exactly what conditions are intended by the recitation of the phrase "dental bacterial disease". Applicant sets forth at page 10, lines 16-18, "The compounds may also be used for other local infections as well as in the treatment of dental bacterial disease, such as gum abscesses, gum disease, gingivitis, and removal, deactivation or killing of plaque biofilms." However, such a

definition is merely exemplary of those conditions that are construed as "dental bacterial diseases", but fails to set forth in any limiting manner those dental conditions that are encompassed by the term such that one of ordinary skill in the art would have been reasonable apprised of the metes and bounds of the claimed subject matter for which Applicant is seeking protection.

Claim 79 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant recites in the last line of present claim 79, "activating said compound by means of light". However, it is not clear what relationship the light has to the claimed dye compound that has been applied to the surface or fluid to be sterilized. The limitation "by means of light" does not set forth how the light is used in order to activate the claimed dye compound of Formula (I).

Additionally, it is noted that present claim 79 reads upon a method for sterilizing a surface or fluid. However, Applicant has failed to connect the preamble objective of sterilizing the surface or fluid to the surface or fluid to be treated. In other words, it is not clear whether the surface or fluid is actually in need of sterilization or whether it is simply any surface or fluid.

Claim 84 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out or distinctly claim the subject matter which Applicant regards as the invention. Present claim 84 reads upon a method for sterilizing fluids comprising contacting the fluid with a conjugate or composite formed between a compound of Formula (I) and a

polymer. However, Applicant has failed to connect the preamble objective of sterilization to the fluid to be treated. In other words, it is not clear whether the fluid is actually in need of sterilization or whether it is simply any fluid.

Claim 89 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out or distinctly claim the subject matter which Applicant regards as the invention. Regarding the limitation "a therapeutically effective amount", Applicant's attention is directed to the MPEP at §2173.05(c)(III), which stated, "The phrase "an effective amount" has been held to be indefinite when the claim fails to state the function which is to be achieved and more than one effect can be implied from the specification or the relevant art. *In re Fredericksen* 213 F.2d 547, 102 USPQ 35 (CCPA 1954)."

The recitation of the administration of therapeutically effective amount of a compound of formula (I) as stated in present claim 89 fails to delineate the function of the effective amount. Applicant has failed to connect the preamble objective of treating to the dose for which it is therapeutically effective. As a result, it is not clear as to what condition(s), disease(s) or disorder(s) of the host upon which the compound is therapeutically effective. It is necessarily implied from the present claims as written that the amount of the compound of formula (I) is intended for use to elicit a therapeutic effect. However, Applicant's failure to define for what the amount of the compound of formula (I) is therapeutically effective renders the claim vague and indefinite.

Regarding the preamble objective of "treatment of microorganisms", Applicant has not clearly, deliberately or precisely set forth the express therapeutic objective that is intended by the

claim. For example, it is not clear whether the method is intended to treat an infection or the mere presence of a microorganism on or in a subject or even the presence of a microorganism in the environment surrounding the subject. In other words, it is unclear as to what express therapeutic end the presently claimed dye compounds are actually being administered to achieve.

Claim 93 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out or distinctly claim the subject matter which Applicant regards as the invention.

Applicant has also failed to set forth in a reasonably clear, deliberate or precise manner what types of lesions would be included or excluded from the phrase "other local infections" such that the skilled artisan would have been reasonably apprised of the metes and bounds of the claimed subject matter and would have been able to readily determine what would constitute infringement of the present claims.

The present disclosure discusses a number of different types of lesions within the present disclosure, including but not limited to, those local infections of hair, nails, skin, stomach, or ear, nose and throat, and other localized infections, such as tinea pedis, candida vulvovaginitis, psoriasis, acne, vitiligo, eczema, etc. (see paragraph bridging pages 9-10), but such discussion is merely exemplary of infections that are intended to be encompassed by the term "other local infections". Applicant fails to provide a limiting definition as to what other local infections are included or excluded by the presently claimed methods. As a result, Applicant's failure to set forth a reasonably clear, deliberate or precise definition of what local infections are encompassed by the claims leaves such a limitation open to subjective interpretation, and fails to clearly

delineate the metes and bounds of the presently claimed subject matter, which is inconsistent with the tenor and express requirements of 35 U.S.C. 112, second paragraph.

It is also noted that Applicant has not set forth in a clear, deliberate or precise manner exactly what conditions are intended by the recitation of the phrase "dental bacterial disease". Applicant sets forth at page 10, lines 16-18, "The compounds may also be used for other local infections as well as in the treatment of dental bacterial disease, such as gum abscesses, gum disease, gingivitis, and removal, deactivation or killing of plaque biofilms." However, such a definition is merely exemplary of those conditions that are construed as "dental bacterial diseases", but fails to set forth in any limiting manner those dental conditions that are encompassed by the term such that one of ordinary skill in the art would have been reasonable apprised of the metes and bounds of the claimed subject matter for which Applicant is seeking protection.

Claim 95 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out or distinctly claim the subject matter which Applicant regards as the invention. In particular, it is noted that present claim 95 is directed to a "method of sterilization of surfaces and fluids". It is not clear whether the method as written is intended to encompass only those circumstances where surfaces and fluids are sterilized in combination (i.e., because the limitation of "surfaces and fluids" requires that both a surface and a fluid be present), or whether Applicant actually intends the claim to read on either the sterilization of a surface or the sterilization of a fluid.

Additionally, present claim 95 reads upon a method for sterilizing surfaces and fluids

comprising applying or contacting the surface or fluid to be sterilized with a photoactivated antimicrobial agent comprising a compound of Formula (I). However, Applicant has failed to connect the preamble objective of sterilization to the surface or fluid to be treated. In other words, it is not clear whether the surface or fluid is actually in need of sterilization or whether it is simply any surface or fluid.

Conclusion

Rejection of claims 77-79, 84, 89-91, 93 and 95 is proper.

Claims 44-53, 65-76, 80-83, 85-88, 92, 94 and 96-97 remain **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

August 5, 2006

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER